Endoscope

with disposabl cartridg for the invagination of endoscopic tube

This is the continuation of application PCT/LV98/00006 based on the priority applications P-97-190 from 03.10.97 (LV), P-98-188 from 23.09.98 (LV) and inventor's certificate № 1522466 from 21.08.78 (SU).

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention pertains to the field of medicine, namely to colonoscopy and enteroscopy, but can also be used for industrial endoscopes.

2. Description of Background Art

The common feature of the known patents and of the solution proposed in this application is the presence of the everted tube, which transportates endoscopic tube. The everted tube invaginates endoscopic tube into the explored channel and therefore was named as invaginator by me. For colonoscopy and enteroscopy one or another combination of invaginator with endoscopic tube must ensure the constantly opened objective of endoscopic tube. This purpose is pursued by the devices under the patents US 4,321,915 and US 4,615,331.

In these devices invaginator is placed on the endoscopic tube by long layers in parallel to tube. After pressure feeding into the everted part of invaginator the inner part of invaginator tightly clings to the endoscopic tube. As the result, the length of endoscopic tube entered into the explored channel, is twice longer as the length of the everted part of invaginator.

Invaginator according to the patent US 4,321,915 is mono-layered. Its doubled lag from endoscopic tube the authors suggest to remove by the periodical change of pressure and vacuum and by extracting of endoscopic tube till its objective coincides with the place of evertion of invaginator. But invaginator is the thin-walled tube. As a result the endoscopic tube will be extracted together with invaginator. Besides, it seems to be complicated to make the exact coincidence of objective with the place of evertion of invaginator.

Invaginator according to the patent US 4,615,331 is multi-layered, in other words it is made in the shape of overlying layers, whose length as one can see on the drawings, is 7 times larger than the diameter of endoscopic tube. Invagination of endoscopic tube with its help will be uneven, as the place of evertion of invaginator will be periodically moved away from the objective. The uneven introduction of endoscopic tube will complicate the examination. Another, more important defect of multi-layered invaginator - the inconsequent unreeling of its layers. The premature everting of lower layer will exclude or complicate eveting of the others.

The named drawbacks exclude the possibility of clinical application of the known invaginators for the transportation of endoscopic tube.

The main drawback of widely applied manual colonoscopes - difficulties of their introducing.

The second drawback is that bending of their distal end is possible only until a definite number of flexures of an endoscopic tube. Its end is bent by rotating of two rollers each connected to its pair of traction lines. Springs, which comprise traction lines, on the distal end continue channels in the wall of cardan-jointed rings. Ends of traction lines are soldered to the distal ring of the cardan executive mechanism for bending the distal end of the tube. Outward extraction of traction lines from the spring decreases gaps between cardan rings and forms a small radius of a flexure. Herewith the distal cardan ring pulls the opposite traction line in distal direction, thus ensuring an increase of space between rings. Difference of lengths of big and small half-circumferences of the tube's bend is a product of «π» and diameter of an endoscopic tube. Japanese authors point out that when 3-4 loops are formed, the distal end of an endoscope is blocked, but biopsy forceps continue to function. This difference is explained by L. Aler formula

$$\frac{Q_1}{Q_2} = e^{\alpha \cdot f},$$

where: «Q_1» - manual power realizing traction lines extraction; «Q_2» - remaining from «Q_1» power, attached to a distal cardan ring or cutters of biopsy forceps; «e» - basis of natural logarithm; «α» - traction line rotations in radians; «f» - friction index between a traction line and a spring. Under fixed values «Q_1» and «f», value «Q_2» depends on value «α», but for two consecutively connected traction lines of an endoscope the latter is twice as large as for one line of biopsy forceps.

The third drawback of the known endoscopes are problems of their maintenance. For recurrent use an endoscopic tube is washed, disinfected and sterilized. However, there are reported cases of infecting patients with AIDS and other infections after endoscopy.

It has been practically proved that if an endoscopic tube has more than 3-4 loops, it is impossible to introduce biopsy forceps into it and take bioptate. This is the fourth drawback of the prototype.

SUMMARY OF THE INVENTION

The invention mainly pertains to the field of medicine and is intended, particularly for the early diagnostics of colon cancer.

The objectives of the invention have been: - ensuring of reliability, evenness and easiness of introduction of flexible endoscopic tube into flexuous channel due to the folded structure of invaginator and ensuring of invaginator's evertion directly under the objective; - ensuring of bending of the distal end of endoscopic tube in flexuous channel; - making maintenance of an endoscope more convenient; - performing biopsy in flexuous channel.

Implementation of these objectives will make colonoscopy available to any physician and will make it easier for experienced endoscopists.

These objectives have been achieved by the fact that the claimed endoscope comprises:

- an invaginator made of everting tube, arranged by pleats, formed in the shape of compact hollow cylinder;
- a disposable cartridge combining the invaginator with auxiliary elements;
- an endoscopic tube ensuring fixation of a cartridge;
- a mechanism for introduction of tube, ensuring together with a cartridge insertion of a tube;
- a system of extraction-intraction of traction lines ensuring bending of the tube's distal end with hydro-manual or pneumo-manual or hydraulic or pneumatic drive;
- a hydraulic or pneumatic intensifier of introduction and extraction of biopsy forceps and hydraulic or pneumatic intensifier of traction line of biopsy forceps.

A compact hollow cylinder of the invaginator can be formed of tightly compressed in longitudinal and transverse directions pleats of different forms of an eversible thin-walled tube placed at any angles with the longitudinal axis of an endoscopic tube. The cylinder has recurrent narrowings of an external diameter and widenings of its internal diameter.

A disposable sterile cartridge for invagination consists of a shell which has a projection at its proximal end, comprising: an invaginator; a compressed spring; its fixator; a spring distancer in which the distal seal of the endoscopic tube is located, which is joined to an uneverted end of the invaginator; a preservative of the distal part of the endoscopic tube joined at the proximal end to a spring stop, but at the distal end - to the tip with elements for hermetic joining to the endoscopic tube, while on the shell is located a proximal seal of the endoscopic tube with the anal dilator having the channel in its wall, but at the distal end of the shell the everted end of the invaginator is fastened. In addition to elements for hermetical joining to the endoscopic tube, the tip may have a protective glass and a channel for glass washing.

An endoscopic tube is supplemented with: - an internal transverse pleats of its external cover; - two air-ducts, the larger one has a lateral opening into the cavity of the proximal seal of the disposable cartridge for invagination, but the smaller - into the cavity of distal and proximal preservatives; - areas for hermetical fixation of preservatives' ends; - a proximal preservative.

The mechanism for introduction of the endoscopic tube consists of the cylinder with two pistons, which are interconnected with distancers and an elastic tube. The cylinder is joined with the cartridge for invagination of the endoscopic tube. The cavity between pistons and the elastic tube is connected to the source of pressure or atmosphere (negative pressure) through the cock. The cavity between the distal piston and the proximal seal of the endoscopic tube through the cock is connected to the source of negative pressure or atmosphere (overpressure). The cocks can be placed in the pedals but the spring, which returns pistons to their home position can be located in the cavity between the proximal seal of endoscopic tube and the distal piston.

The system of extraction-intraction of traction lines ensuring management over the endoscopic tube's distal end, has a hydro-manual or pneumo-manual or hydraulic or pneumatic drive and creates exertion at the distal end of traction lines. The system includes sources of overpressure and negative

pressure connected to tubes. At the distal end of the tube and traction line a cylinder can be placed whose piston is connected to a traction line. The unit cylinder/piston can be placed by sylphon,

A manual extractors-intractors of traction lines could be made in the manner of a rod, but the sources of overpressure and negative pressure – in the manner of a piston and cylinder, positioned on the rod. An element ensuring synchronous feeding of negative pressure into the cavity of extracted traction line and overpressure into the cavity of introduced traction line could be a pinion mated with cogs of two rods. As each of two pinions is coupled only with its pair of traction lines, the bending of the tube's end is performed in two stages. The cross-piece with a management lever, whose central part has a movable connection with the body of the desk node of control block, but the ends are attached to four rods, pistons and cylinders, ensures simultaneous bending of the tube's distal end in any direction.

A hydraulic or pneumatic intensifier of introduction and extraction of biopsy forceps includes sources of overpressure and negative pressure, which are connected through a cock to the cavity of the biopsy channel, the entrance to which is sealed with a seal of biopsy forceps, at the distal end of which there is a piston of the biopsy channel. In addition the biopsy forceps have an intensifier of traction lines and contain a flexible hermetic tube, which is connected to sources of overpressure and negative pressure, but the distal end of the tube and traction lines finishes with a cylinder and a piston respectively. The unit piston/cylinder is possible to replace with a segment of sylphon, the distal end of which is connected to traction lines.

BRIEF DESCRIPTION OF THE DRAWINGS

The graphic materials illustrate the essence of invention, where on the FIG.1 is represented the endoscope with disposable cartridge for invagination, where: a - handle-shaped control block; b - distal part of endoscopic tube with mounted cartridge; c - longitudinal section of cartridge; d, e, f - enlarged fragments of FIG.1c. On FIG.2 is shown the system of extraction-intraction of traction lines bending the distal end of endoscopic tube, when the distal end is in direct position, where: a - position of system elements comprised in control block; b - enlarged fragment of fig.2a; c - distal part of tube with "bared" system elements (vertical arrows show the top-bottom of endoscopic tube); d – enlarged fragment of FIG.2c. On FIG.3 is represented the system of extraction-intraction of traction lines when the end of an endoscopic tube is bent downwards, where: a - position of elements contained in control block; b - enlarged fragment of FIG.3a; c - distal part of endoscopic tube with "bared" elements (horizontal arrows show the direction of traction lines motion); d, e - enlarged fragments of FIG.3c. On FIG.4 are represented: a - control block and design of new endoscope; b - cross-piece with lever, rods, pistons and cylinders; c – construction of a mechanism for introduction of endoscopic tube into cartridge; d - intensifier of introduction and extraction of biopsy forceps.

DESCRIPTION OF THE PREFFERED EMBODIMENT

The list of numerical markings of FIG.1-4 is given at the end of the specification. A new endoscope comprises endoscopic tube 3 with control block 2 and communication branch. Air-duct 15 and cock 17 positioned on control block 2 or in pedal, connect source of working pressure with opening 21 into the cavity of seal 13, which communicates with cavity 14 of shell 22. The distal part of shell 22 is commensurable in relation to length and diameter to uneverted part of invaginator 23, but the

proximal part – to the compressed spring 10. Everted end 12 of invaginator 23 is connected to shell 22 by ring 16. Invaginator 23 has narrowings and widenings 24, as well as gap 25 with distal preservative 26. Ends of distal 26 and proximal 27 preservatives and corresponding to them places of tube 3 have areas 28 for interconnection and hermetization. Seal 29 on end 7 of invaginator 23 separates cavity 14 from cavity 25, which communicates with the intestinal cavity. A distancer 30 prevents deformation of seal 29 by spring 10. Ends of compressed spring 10 are based on distancer 30 and stop 11 at the end 28 of preservative 26. Stop 11, in its turn, is positioned on the projection 31 of shell 22. The distal end of preservative 26 ends with tip 6 with channels 32 for washing of protective glass 33 and blowing-up of intestines, as well as an element for connection to endoscopic tube 3. On the border of narrow and broad parts of shell 22 there is an area of intermediate diameter with indented elastic ring 34 for fixation of compressed spring 10. Channel 35 of anal dilator 19 is used for decompression of intestines during intubation. In the tube 3, besides the enumerated, there are elastic tubes 36, 37 comprising springs 38, 39 and traction lines 40, 41. Tubes 36, 37 are connected to springs 38, 39 with thread 42. Near mechanism 43 for bending the distal end of tube 3, ends of tubes 36, 37 are closed with plugs 44, which also connect springs 38, 39 with traction lines 40, 41. Proximal ends of tubes 36, 37 are connected with sources 45 of overpressure and negative pressure. Proximal ends of traction lines 40, 41 are connected with their manual extractors-intractors 46, but the latter - with element 47 which ensures synchronous feeding of negative pressure into the cavity of traction line 40 which is being extracted and of overpressure into the cavity of traction line 41 which is being introduced. Endoscopic tube 3 has internal pleats 48 of external cover, air-duct 49 with two openings 50 for vacuum fixation of preservatives 26, 27 to tube 3 and also has removable sleeve gasket 51. Control block 2 has cock 52 of air-duct 49. Seal 13 is hermetically connected to mechanism 53 for introduction of endoscopic tube 3. Mechanism 53 for introduction of tube 3 is operated by pedal 54 but lever 55 realizes bending of tubes end. Cylinder 56, two pistons 57, distancers 58 and elastic tube 59 limit cavity 60, which is connected with source of overpressure by means of cock in pedal 54. Cavity 61 comprises return spring 62 and is connected with negative pressure source by means of cock in pedal 54. Seal 64 and nut 65 are mounted on biopsy forceps 63, but piston 66 is positioned at their distal end. Seat for seal 64 and nut 65 is located at entry 67 to biopsy channel, which is positioned with cock 68 on control block 2. Sylphon 69, which serves as source of overpressure and negative pressure in the intensifier of traction line of biopsy forceps 63, can be combined with its handle.

Marks made on preservative 27 and tube 3 serves for their correct positioning. Then mechanism 53 is mounted on tube 3 and cartridge for invagination is fixed. Pressing of cock 52 will ensure vacuum fixation of preservatives 26, 27 to tube 3. After introduction of seal 13 into cylinder 56 endoscope preparation for work is completed.

After the patient has been placed on an endoscopic table a cartridge is oiled and introduced into the rectum and its ampoule is examined as if with a rigid rectoscope. The pressure in cavity 14 is raised by pressing cock 17 thus freeing distancer 30 from coupling with fixator 34 and shell 22. Thereby spring 10 is released and it is possible to proceed with invagination of tube 3. Eversion of invaginator 23 and introduction of tube 3 into the colon occurs under working pressure in cavity 14 at the moments of pressing pedal 54. During endoscopy intestines are to be distended. Gas into intestines is constantly supplied through gas/liquid channel of tube 3 and through channel 32 of tip 6 thus preventing intestinal

content of getting under protective glass 33. Gas evacuation from intestines occurs through channel 35 of anal dilator 19.

Bending of mechanism 43 is realized by means of overpressure and negative pressure sources 45, manual extractors-intractors 46 of traction lines 40, 41 and by means of elements 47 which ensure feeding of negative pressure in the cavity of tube 36 which comprises extracted traction line 40, and feeding of overpressure in the cavity of tube 37 containing introduced traction line 41. Due to negative pressure elastic tube 36 and spring 38 are shortened. Considering, that their distal end is connected with traction line 40, this shortening relieves its manual extraction. Due to pressure in tube 37 the latter and spring 39 elongates towards executive mechanism 43 thus relieving manual intraction of traction line 41. Thread 42 twisted on tubes 36, 37, connects them with springs 38, 39. Thus, negative pressure and overpressure which shorten and elongate tubes 36, 37 and springs 38, 39 ensure application of powers to distal ends of traction lines 40 and 41; manual extraction and intraction of traction lines 40, 41 creates synchronous efforts on their proximal ends. Mechanism 43 of tube 3 is bent downwards by the above-mentioned method. During bending of mechanism 43 upwards all above enumerated elements are moved in opposite directions, but bending of mechanism 43 to the left and to the right is implemented by the second pair of traction lines which work similarly. In intermediate positions mechanism 43 is bent by interchangeable application of both pairs of traction lines. Element 47 made in the shape of a cross-piece with lever 55 ensures simultaneous bending of mechanism 43 in any direction.

As during colonoscopy tube 3 repeats all natural flexures of the colon its extubation must not be accelerated. Anal dilator 19 through which extubation is to be conducted eliminates unpleasant sensations caused by this process.

The most practically important version of the invention is a colonoscope with endoscopic tube 3 without biopsy channel. A disposable cartridge ensures an available to all and atraumatic transportation of tube 3 in the colon, preservatives 26, 27 protect the patient from infections seated in endoscopic tube 3, but tube 3 - from getting contagious during endoscopy. Ergonomy of handling such colonoscope also makes it available to any physician: during endoscopy a physician in sedentary position, watches the screen, presses pedal cock 17 with one foot, pedal 54 with another, the right hand controls lever 55, but in case of necessity washes the protective glass 33 by pressing on the cock with the left hand. Such colonoscope is necessary firstly for family doctors, gastroenterologists and surgeons for regular screening of colon cancer. Having selected "suspicious" patients out-patient physicians will direct them to an in-patient clinic for conducting biopsy and other thorough examination.

For realization of biopsy a cartridge with tip 6, without glass 33 is used. Having exhausted the possibility of manual insertion of forceps 63, it is necessary by means of seal 64 and nut 65 to hermetize entry 67 into the biopsy channel and connect it by means of cock 68 to the source of pressure. Further insertion of forceps 63 is performed by their manual intraction and due to pressure of liquid or gas on piston 66, but extraction – by switching cock 68 in the position «vacuum» and manual extraction of forceps 63. Due to location of source 69 of overpressure and negative pressure of traction line intensifier in the handle of forceps, taking of bioptate is made as

previously - approach of rings ensures movement of the traction line inwards, but detachment - extraction of the traction line.

Specifications of graphic materials' marks on FIG.1-4:

2 - control block with communication branch;

3 – endoscopic tube;

6 - tip of endoscopic tube 3;

7 - uneverted end of invaginator 23;

10 - compressed spring;

11 - stop for spring 10;

12 - everted end of invaginator 23;

13 – proximal seal of tube 3;

14 - cavity of everted part 4 of invaginator 23;

15 – air-duct for feeding working pressure into cavity 14;

16 - ring, fixing end 12 of invaginator 23;

17- cock of air-duct 15;

19 - anal dilator;

21 – air-duct 15 opening on tube 3;

22 - shell of cartridge for invagination;

23 - invaginator formed in a compact flexible cylinder;

24 - narrowings and widenings of cylinder of invaginator 23;

25 - gap (cavity) between cylinder of invaginator 23 and preservative 26;

26 - distal preservative of tube 3;

27 - proximal preservative of tube 3;

28 - areas on tube 3 and at the ends of preservatives 26, 27 for their hermetic connection;

29 – distal seal between tube 3 and end 7 of invaginator 23;

30 - distancer between spring 10 and invaginator 23 comprising seal 29;

31 - projection on shell 22 for stop 11;

32 - channel in tip 6;

33 - protective glass of tip 6;

34 - elastic ring, fixing spring 10 in compressed state;

35 - channel in anal dilator 19;

36 - lower elastic tube of extractor-intractor of traction lines;

37 - upper elastic tube of extractor-intractor of traction lines;

38 - lower spring of extractor-intractor of traction lines;

39 - upper spring of extractor-intractor of traction lines;

40 – lower traction line of extractor-intractor of traction lines;

41 – upper traction line of extractor-intractor of traction lines;

42 - thread fixing elastic tubes 36, 37 to springs 38, 39;

43 – mechanism for bending of distal end of tube 3;

44 - plug closing tubes 36, 37 and connecting springs 38, 39 with traction lines 40, 41;

45 - sources of overpressure and negative pressure;

46 - manual extractors-intractors of traction lines 40, 41;

47 – element for extraction-intraction of one or two pairs of traction lines;

48 - pleats of external cover of tube 3;

49 – air-duct into cavity of preservatives 26, 27;

50 - distal and proximal openings of air-duct 49 on tube 3;

51 - sleeve gasket;

52 – air-duct 49 cock on control block 2;

53 –mechanism for insertion of endoscopic tube 3;

54 – pedal for switching on mechanism 53;

55 - lever of element 47, made in a shape of cross-piece;

56 - cylinder of mechanism 53;

57- pistons of cylinder 56;

58 – distancers between pistons 57;

59 - elastic tube, attached to pistons 57;

60 - hermetic cavity, enclosed by elastic tube 59 and pistons 57;

61 - hermetic cavity, enclosed by seal 13 and distal piston 57;

62 - spring returning pistons 57 to home position;

63 - biopsy forceps;

64 - seal of entry 67 into biopsy channel;

65 - nut, fixing seal 64;

66 - piston of biopsy forceps;

67 - entry into biopsy channel;

68 - cock feeding the overpressure or negative pressure into biopsy channel;

69 - source of overpressure and negative pressure connected with cavity of biopsy forceps 63.

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